Cluster Randomized Trial Evaluating Impact of a Community-based Microfinance Scheme on Childhood Nutritional Status

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SUMMARY

The objective of this cluster randomized trial was to determine if Rojiroti microfinance, for poor Indian women in the state of Bihar, improves child nutrition. Women with children under 5 years formed self-help groups, and saved their money to provide loans to group members. After an interval of 6 months, they received larger external loans and *tolas* were randomized to receive Rojiroti immediately or after 18 months. The primary outcome measure was mean weight for height Z score (WHZ) of children under 5 years in the intervention *versus* control *tolas* who attended for weight and height measurement 18 months after randomization. Total 28 *tolas* to each arm were randomized and data were collected from 2469 children (1560 mothers) at baseline and 2064 children (1326 mothers) at follow-up. WHZ was calculated for 1718 children at baseline and 1377 (674 intervention and 703 control) at follow-up. At 18 months, mean WHZ was significantly higher for intervention (–1.02) *vs* controls (–1.37; regression coefficient adjusted for clustering b=0.38, 95% CI 0.16 to 0.61, *P*=0.001). Significantly fewer children were wasted in the intervention group (122, 18%) *vs* control (200, 29%; OR=0.46, 95% CI 0.28 to 0.74, *P*=0.002. The authors concluded that in marginalized communities of rural Bihar, child nutrition was better in thosewho received Rojiroti microfinance, compared with controls.

COMMENTARIES

Evidence-based Medicine Viewpoint

Relevance: Childhood malnutrition is a clinically and socially significant problem in many resource-constrained settings in the world. Besides affecting individual children and families, it has far reaching consequences on society in general. Naturally, its alleviation depends on many factors beyond nutritional supplementation (of children and their families). A recent collaborative study [1] by a group of researchers from the United Kingdom, non-governmental organizations and Patna Medical College, explored whether financial empowerment of women in disadvantaged rural communities (through the Rojiroti scheme) could impact the nutritional status of their children. In this scheme, women form self-help groups voluntarily, attend meetings regularly, contribute a nominal sum weekly, become eligible for very small loans from the pool of collected funds, and after six months can obtain loans up to Rs 3000 based on credit-worthiness. There is no restriction on what the loan amount can be used for. The investigators chose a cluster randomized trial design to compare rural units (described as *tolas*) that implemented the Rojiroti scheme with *tolas* that did not. Anthropometric measurements of children younger than five years old in both trial arms were done at enrolment, repeated after 18 months, and compared between the arms. Although a research question was not articulated by the investigators [1], it can be framed as: What is the effect of community-based Rojiroti microfinance scheme (I = Intervention) on the nutritional status of under-five children (O=Outcome), in economically and socially disadvantaged communities in rural Bihar (P=Population) compared to no microfinance scheme (C=Comparator) at the end of an 18 month period (T = timeframe of outcome assessment)?

Critical appraisal: ***Box* I** presents a summary of the trial design and main results. The investigators chose a cluster RCT design to address the research question. Technically, this is the ideal design to evaluate efficacy of potential interventions in clusters of individual participants, wherein the effects (of the intervention) are expected/anticipated to spill over into/onto those who are not directly receiving the intervention, but are present in the same cluster. However, if the effect of the intervention is expected to have limited impact on non-participating individuals in the cluster, then an individual RCT is more appropriate. It is difficult to judge which of the two designs is superior to compare community effects through individual empowerment of some members, as was done in this trial [1].

The investigators used a computer program for randomizing pairs of *tolas*, although since only two *tolas* were randomized at a time, simple coin tossing is sufficient. Paired randomization obviated the scope for

Box I Summary of the Trial

Study design: Cluster randomized trial with allocation of rural community units called *tolas* into the trial arms. The intervention was on women in the *tolas*, and the outcomes were measured in their children.

Study setting: Four tehsils of Patna district comprising about 60 *tolas*. A tola is described as a rural community with a population of approximately 500 people with similar social and economic background [1]. In general, the communities appear to be disadvantaged as evidenced by absence of health-care centres, lack of access to piped water, low level of women's education, social empowerment and economic status. However, all *tolas* had electricity supply and immunization coverage was over 95%.

Study duration: *Tolas* were recruited in three phases, during 2 months in 2012, two months in 2013, and 1 month in 2014. No other details were mentioned.

Inclusion criteria: Sixty *tolas* were selected for implementation of the Rojiroti scheme; however, the basis of selection and/or eligibility criteria were not mentioned. Any woman in the intervention tola could join the Rojiroti microfinance scheme. Women in the Comparison group (i.e control) *tolas* could not join the Rojiroti scheme, but could join other (unspecified) self-help group (schemes). All children <5 years in the *tolas* selected for Intervention and Comparison groups were eligible for outcome measurement, whether (or not) their mothers availed the Rojiroti scheme.

Exclusion criteria: None were described.

Enrolment process: The basis for selection of *tolas* was not specified. *Tolas* of similar size (definition unspecified) but at least 15 km apart, were paired, and randomly assigned to either the Intervention or Comparator group. Enrolment of *tolas* occurred in three phases viz 2 months in 2012 (20 *tolas* included), 2 months in 2013 (30 *tolas* included) and 1 month in 2014 (6 *tolas* included). Women in the Intervention *tolas* were invited to join the Rojiroti scheme through a "show of hands" and their children were enrolled with verbal consent.

Intervention and Comparison groups: The Rojiroti scheme was implemented in the intervention arm *tolas*. Nothing was done in the comparison arm *tolas*. Baseline demographic parameters of the *tolas*, participating women and their children were recorded in both groups. Anthropometric measurements of all under-five children were done using standard tools and methods, at baseline and also after 18 months; in both arms of the trial.

Outcomes: All outcomes were measured 18 months after enrolment, and compared between the two trial arms (*outcomes are listed in the last row*). Definition of two of the secondary outcomes was not provided in the article *viz.,* proportion of women with freedom to travel without permission of a male relative, and forced asset sale.

Follow-up protocol: Research staff conducted anthropometric measurements in all children available 18 months after enrolment of *tolas*, irrespective of whether the children and/or their mothers participated in the trial.

Sample size: A *priori* sample size calculation was performed for a superiority trial, to detect a 0.26 z score improvement in WHZ from an estimated baseline of -0.96, with alpha error 0.05 and beta error 0.20. Assuming 10% attrition, the estimated sample size was reported as 60 *tolas*. The investigators observed approximately 40 under-five children per tola initially, hence assumed that there would be approximately 2400 children for anthropometric measurements across the 60 *tolas*.

Data analysis: Data of available children were analysed between trial arms, calculating unadjusted odds ratio. Subsequently odds ratio was adjusted for baseline nutritional status, age, gender and number of under-five children per family. It was decided post hoc to compare the outcomes in children in Intervention *tolas* whose mothers did (versus did not) join the Rojiroti scheme.

Comparison of groups at baseline:

- The *tolas* in the two arms were comparable for multiple parameters viz connection to a paved road, distance from a main road, presence of public distribution scheme shop, presence of government primary school, presence of other school, availability of primary health centre, access to ASHA worker and ANM, availability of piped water supply, and electricity.
- Participating mothers in the two arms were comparable in terms of the number who joined the Rojiroti scheme and age. However, there were statistically significant differences in terms of family land ownership, freedom to travel without permission, ability to read/write, and school attendance- all in favour of those who were in the Intervention arm.
- Children in the participating *tolas* were comparable in terms of median number enrolled per tola, gender distribution, mean age, proportion delivered at home, immunization status, and proportion having road-to-health cards. Most anthropometric parameters were comparable between arms, however HAZ and the proportion of children with MUAC <12.5cm, were both significantly better in the intervention arm. However, proportion with wasting was significant higher in the Intervention arm.

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***Box I** continued*

Summary of results: Intervention versus Comparison arms

Primary outcome

- Mean (SD) WHZ: -1.02 (1.11) *vs* -1.37 (1.10), uOR* 0.16, 0.61; aOR** -0.03, 0.53

Secondary outcomes

- Mean (SD) HAZ: -2.37 (1.29) *vs* -2.53 (1.25), uOR -0.04, 0.37; aOR -0.24, 0.10
- Mean (SD) WAZ: -2.13 (1.03) *vs* -2.37 (1.05), uOR 0.11, 0.43; aOR 0.04, 0.49
- Mean (SD) MUAC: 13.6 (1.1) *vs* 13.4 (1.1), uOR 0.03, 0.40; aOR -0.14, 0.38
- Proportion with wasting: 18% *vs* 29%, uOR 0.28, 0.74; aOR 0.33, 1.14
- Proportion with stunting: 63% *vs* 66%, uOR 0.60, 1.12; aOR 0.57, 1.64
- Proportion with underweight: 53% *vs* 63%, uOR 0.47, 0.84; aOR 0.29, 0.89
- Proportion with MUAC <12.5 cm:13% *vs* 18%, uOR 0.41, 1.05; aOR 0.27, 2.23
- Proportion with MUAC <11.5 cm: 3% *vs* 5%, uOR 0.36, 1.33; aOR 0.10, 6.14
- Proportion of women with freedom to travel[‡]: 5% vs 5%, uOR and aOR not specified
- Forced asset sale: 2% vs 2%, uOR and aOR not specified

**uOR is the 95% CI of the unadjusted odds ratio; **aOR is the 95% CI of the adjusted odds ratio; [‡]travel without permission of a male relative.*

allocation concealment. The outcome assessors were not blinded to the intervention, but the reasons for this were not specified.

Although, all 56 enrolled *tolas* were present at the end of the study (*i.e*., zero attrition), there was significant attrition amongst individual participants (both mothers and children), between the randomization (*i.e.,* enrolment) step, baseline variable measurement step and outcome assessment step. For example, 2469 children were eligible for anthropometric data assessment across 56 *tolas* at enrolment, but WHZ data could be analysed in only 1718 (69.6%). Similarly, 2064 children were eligible for outcome measurement at the end of the study, but WHZ (primary outcome) could be analysed in only 1377 (66.7%). These attrition rates are considerably high, although they were comparable between the two groups. Further, it is disconcerting that one-third of the potential data was unavailable not because participants dropped out, but because the anthropometric data were not collected properly. This is unacceptable in a well-funded RCT with appropriate training of research staff.

It is also unclear what proportion of the children whose baseline data were collected, underwent data collection at the end of the study. This has two entirely different implications. First, if these proportions are significantly different between the two trials arms, a new confounding variable emerges. Unfortunately, the authors did not show this data. Second, if the intervention (*i.e.,* implementation of Rojiroti micro-finance scheme) is believed to impact the whole community (and not just the participating households), then we would expect to see the benefits in children irrespective of whether or not they were present when the intervention started or whether their families availed the scheme. This seems to have been the assumption of the investigators in this study [1]. But if this is the case, it can be argued that pre and post intervention measurement of anthropometric measurements would be more meaningful than comparison between trial arms.

This raises another important issue. The statistically significant 'benefits' in the Intervention arm were not because children in this arm showed improvement in anthropometric measurements (as one would expect). In fact, 5 of 11 outcomes showed worsening over the 18-month intervention period. These include mean HAZ (declined from -2.00 to -2.37), mean WAZ (declined from -1.89 to -2.13), proportion with stunting (increased from 49% to 63%), proportion with underweight (increased from 44% to 53%) and proportion of mothers with freedom to travel without permission (declined from 8% to 5%). Even the other anthropometric measures showed no improvement, but merely remained unchanged over 18 months. Thus, the Intervention arm was proven superior [1] only because the Comparison arm showed far greater worsening of anthropometric parameters. The authors interpreted this as empowerment of the community to be resilient during food shortage, thus emphasizing the benefit of the Intervention. However, this explanation is unacceptable for three reasons. First, it assumes that under natural circumstances, children's nutritional status declines over time. However, the authors showed no data supporting this presumption [1]. Second, the proportion

of households forced to sell assets was exactly 2% in both arms, suggesting that apparent periods of food shortage did not translate to loss of assets in either arm. Third, analysis of the reasons for taking loans in the Intervention arm shows that a very small proportion was used for food and supplies (in terms of percentage as well as absolute amount).

How to explain the differences in the two arms at the end of the trial? One explanation could be that mothers in the Intervention arm were more empowered than mothers in the Comparison arm (literacy 21% *vs* 16%, school attendance 19% *vs* 13%, and freedom to travel without permission 8% *vs* 3%, and family land ownership 13% *vs* 8%). Perhaps this could account for better child-care practices even in the midst of acute shortages, thereby preventing the pattern of decline seen in the Comparison arm. However, these empowerment indicators were present in less than 20% mothers in the Intervention arm; hence, other unexplored factors are likely. Had the authors re-collected maternal baseline parameters at the end of the study, a clearer picture of women empowerment (if any) could be considered.

It should be remembered that children in the Intervention arm had superior HAZ than those in the Comparison arm. The impact of this on the final outcome is unclear, although height is impacted much later than weight and muscle mass, during food deprivation.

A noteworthy point is that the authors [1] did not report the number of deaths, or medical morbidities amongst the children in either arm. Thus, the data presented pertain only to survivors. It is well-recognized that children with worse nutritional state have greater likelihood of morbidity and mortality. Thus, the available children no longer represent all the eligible children. This compromises internal validity. It can be further argued that all-cause mortality data alone may be insufficient, and malnutrition-related morbidity should also have been measured.

The investigators reported that children in Intervention *tolas* had similar anthropometric outcomes, irrespective of whether or not their mothers participated in the Rojiroti scheme. They suggested that this indicated some kind of community effect spilling over into non-participating households. However, the proportion of participating women in each tola were not described, hence this assumption could be too simplistic.

It appears that 90% children in each arm of the trial possessed road-to-health cards. These cards provide valuable longitudinal anthropometric data. This would have enriched the study by providing some data for drop-out children, internal checks against spurious data collected in the study, and also a 'last recorded' value for those older than 5 years at follow-up. Most important, the inflection time point(s) at which nutritional decline occurred could have been calculated.

Another missed opportunity in this study is that data were not analyzed in age bands, rather all under-five children were clubbed together and treated as single unit. This is important because growth rates vary by age in under-five children.

As in many such studies, interesting data emerged that were not the focus of the investigators. For example, more than 95% children in both arms were immunized [1]. This is somewhat surprising, considering that the overall immunization coverage (with BCG, 3 DPT, and measles vaccine among 12-23-month-old children) in Bihar during 2015-16 was 61.7%, coinciding with the national average of 62.0% [2]. How did the included children have such excellent immunization coverage? This could be because over 90% *tolas* had access to ASHA workers as well as ANM in their community. Or perhaps the reported immunization used some other definition of immunization, or data were collected unreliably. Since the baseline nutritional indicators of children in terms of proportions with stunting, wasting and underweight coincided with the overall NFHS-4 data for Bihar [2], the latter assumptions are more likely.

Each tola had only 500 people and around 40 under-five children. Although the age break-up of the *tolas* is not known, India's population pyramid suggests just under 10% of the population is in the age group 5-9 years [2]. This would translate to about 50 primary school age children in each tola. It is therefore impressive that all *tolas* had a primary school and some had other schools as well.

Conclusion: This cluster RCT [1] suggested that participation of disadvantaged rural women in a specific microfinance scheme could prevent decline in the anthropometric measurements of their under-five children over a period of 18 months. However, the validity of the trial is compromised by methodological issues and compromised power due to significant attrition. Hence it is difficult to draw firm conclusions from this trial or recommend further similar studies.

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Pediatrician's Viewpoint

India is home to about one third of the stunted and half of the wasted under-five children present globally [1]. Malnutrition attributes to about 70% of the under-five deaths in India during 2017 [2]. Apart from morbidities and mortality, malnutrition is a key determinant for optimal cognitive growth and development and overall health and productivity in adulthood [3]. The UN Sustainable Development Goal-2 targets elimination of child malnutrition by 2030 [4]. Child health and nutritional status is reflecting a socioeconomic gradient [5]. The economic growth in recent times has not optimally transformed into reduction in childhood malnutrition [6].

India has been making efforts towards reducing the burden of malnutrition and the health adversities through various programs including the nutrition supplementation and nutrition rehabilitation centers. Recently National Nutrition Mission (NNM, also called Poshan Abhiyan) has been initiated by Government of India, which targets reducing stunting, undernutrition, anemia and low birth weight by 2%, 2%, 3% and 2% annually, respectively by 2022 [7]. Globally, several efforts in past have targeted the nutritional status of children and women through various livelihood, agricultural and conditional cash transfer systems with varied results [8].

The current study documented the impact of the Rojiroti microfinance effort through Self help groups in Patna district, Bihar over 18 months period [9]. Although this study was conducted in Bihar, the context and underlying factors are applicable to several parts of India. Malnutrition is a constant challenge for the pediatrician. In clinical practice, the pediatricians assess nutritional status and give nutritional counselling including breastfeeding, but the real change in family practice and nutritional status dependents on the food security, availability and home food environment. Research from India revealed the roles of social and economic competing forces for persistence of undernutrition [10]. Although this article does not include clinical dimension, but has relevance for the pediatricians and child health and nutrition functionaries.

The pediatricians have multiple opportunities and roles to play in this context for all categories of clients, especially those from the weaker social and economic strata. Age-appropriate counselling and empowerment of the parents and families for preventive care including nutritional practices (breastfeeding, weaning and complementary feeding, especially targeting the locally available nutritious foods ingredients), routine immunization, vitamin A and deworming schedule and general hygiene and sanitation at household level must be practiced by all pediatricians. Rational medication and supplementation prescription practice can be critical in minimizing the out of pocket expenses for the families. Apart from the prescription, appropriate counselling for medicine and supplementation adherence and continued feeding during and after the illness are to be emphasized.

The pediatricians also have a stewardship role in healthcare financing. While major share of the curative healthcare services is provided by the private sector, the preventive services are delivered by public sector. Out of pocket expenditure (OOPE) amounts to about 75% of healthcare expenditure in India and the catastrophic healthcare expense is an important cause of impoverishment for the families [11]. The catastrophic health related OOPE was also observed in the current study [9]. Thus, the treating pediatrician has a responsibility to understand the financial implications of their clinical decisions. The communication by the pediatricians to be effective for parents, family and the community, it must be clinically appropriate, transparent and sociocultural context compatible.

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Nutritionist's Viewpoint

Childhood malnutrition is increasingly recognized as an important public health problem, for its adverse effect on health and child survival, as well as for long term growth and development. India is at the epicentre of this global public health problem, with 22 million children wasted and over eight million severely wasted at any one time [1]. Hence implementation of evidence-based strategies for prevention and management is topmost priority for increasing child survival and productivity.

Malnutrition is a complex and multi-dimensional issue, affected by poverty, inadequate food consumption, inequitable food distribution, suboptimal infant and child feeding and care practices, equity and gender imbalances, poor sanitary and environmental conditions and limited access to quality health, education and social services. Social protection involves policies and programs that protect people against vulnerability, mitigate the impacts of shocks, improve resilience and support people whose livelihoods are at risk. Social protection programs can improve food security at household level, quality, and diversity; decrease undernutrition; and help children reach their full potential [2].

In the present study [3], authors assessed the effect of microfinance initiative on the nutrition status of children in a marginalized population. The study suggests that, though micro-finance has been able to reduce the deterioration in nutrition levels in the children of extremely poor families, it has not been able to actually improve or even maintain the nutrition levels. This may be due to the low-income gains from the scheme. From a policy point of view, there are important conclusions which may be drawn. One inference which may be drawn is that schemes which directly tackle malnutrition and help provide food to children must be continued and encouraged in the poor states of the country.

Many nutrition-specific interventions to prevent wasting and other forms of malnutrition are delivered at community-level in India through Anganwadi Services under the umbrella of the Integrated Child Development Services (ICDS) scheme. Nutrition-specific interventions are also delivered during the VHSND or on separate days, including growth monitoring, the promotion and support of infant and young child feeding (IYCF), micronutrient supplementation and supplementary feeding. While the schemes, programs and delivery platforms are nationwide in scale, the coverage, and quality of interventions are insufficient to achieve the impact required. It would be beneficial to channelize efforts and funding to boost the efficacy of such schemes.

To conclude, while microfinance schemes have their own importance, they may not be the way to address nutritional issues among children. A truly multi-sectoral approach will achieve optimal nutrition outcomes through greater coverage.

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